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APR 30 2008

SMDA REQUIREMENTS – K080845

510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS
ORwell™ Fluid Collection and Disposal System

Manufacturer:	Cardinal Health Corporation 1500 Waukegan Road MP/WM Mc Gaw Park, IL 60085
Regulatory Affairs Contact:	Lavenia Ford 1500 Waukegan Road MP/WM Mc Gaw Park, IL 60085
Telephone Number:	(847) 785-3323
Date summary Prepared:	March 5, 2008
Trade Name:	ORwell™ Fluid Collection and Disposal System
Classification:	Class II per 21 CFR § 878.4780
Classification Name:	Powered Suction Pump
Predicate Device:	K012991 - Stryker Neptune Waste Management System and K040239 - Neomedix Corp. Supraflow Console

Description:

The Disposal Station is a stationary unit located in a utility area. The ORwell™ Fluid Collection and Disposal System consists of three (3) components:

1. Mobile Unit
2. Disposal Station
3. Disposable Collection Disc (hereinafter referred to as "Disposable Disc," "Collection Disc," or "Disc")

The Mobile Unit is a portable unit that provides its own source of vacuum and houses the Disposable Collection Disc which is used to collect fluid waste and small debris from the surgical site. The amount of suction can be regulated by the end user via the simple user interface on the Mobile Unit.

The Disposable Collection Disc is a single use disposable that collects fluid waste from the surgical procedure. It has four ports to allow for the collection of fluid from various instruments during the procedure. Additionally, the Disc features an attached flexible liner in which collected fluid is contained.

The Disposal Station is a stationary unit located in a utility area plumbed with water inlet and outlet lines. After the surgical procedure, the Mobile Unit is moved to the utility area where it interfaces with and locks into the Disposal Station. After the Mobile Unit is locked into place, the

Disposal Station automatically empties the Collection Disc, sending the surgical fluid waste into the hospital's waste water system. The evacuation process also collapses the Disc to allow for easy disposal.

Intended Use: The ORwell™ Fluid Collection and Disposal System is intended to be used in the Operating Rooms, Surgical Centers and Doctors' Offices to collect and dispose of fluid waste.

Substantial Equivalence

The ORwell™ Fluid Collection and Disposal System is substantially equivalent to the Neptune Waste Management System in that:

- Intended use is a subset of that of the Neptune Waste Management System. Removal of the smoke evacuation feature limits use within the currently cleared indications of the predicate device. This change does not raise new risks to the patient or clinician, nor is there any significant effect on the device's safety or effectiveness with respect to surgical fluid collection.

- Performance attributes and safety components are substantially equivalent to the predicate
  - Vacuum range is the same as predicate
  - Both devices regulate vacuum via a knob-controlled bleeder valve
  - Both devices assure HEPA quality exhaust
  - Both devices contain an overflow prevention mechanism

- The ORwell™ System differentiates from the predicate in that its collection vessel is a single use disposable component. This requires the user to dispose of all components that have come in contact with surgical fluid waste between procedures, limiting likelihood of cross-contamination. This key feature change increases the safety of the device and has no adverse effect on substantial equivalence.

The following performance attributes were found to be acceptable for the intended use.

Note tables below:

Design Feature	**Proposed Device** Cardinal ORwell™ Surgical Fluid Waste Collection and Disposal System	**Predicate Device** Stryker Neptune Waste Management System (K012991)	**Predicate Device** Neomedix Corporation, SupraFlow Console (K040239)	Comments
Indications for Use	The Cardinal ORwell™ System is intended to be used in the Operating Room, Surgical Centers, and Doctor's Offices to collect and dispose of surgical fluid waste.	The Neptune Waste Management System is intended to be used in the Operating Room, Surgical Centers and Doctor's Offices to collect and dispose of surgical fluid waste as well as collect smoke generated from electrocautery or laser devices.	The NeoMedix SupraFlow Console is an aspiration pump intended for use in general surgery applications where aspiration of irrigation and waste fluid from a surgical site is desired. The device is not indicated for liposuction use.	The new device and the predicate K040239 have the same claim of removing fluid.
Closed System	Protects hospital personnel from (1) the splashes and inadvertent biohazard exposure that are possible with suction canister devices and (2) the cross-contamination and cleanliness issues that are possible with fluid collection and disposal systems that utilize a reusable collection chamber	Protects hospital personnel from splashes and inadvertent biohazard exposure that is possible with suction canister devices	-	The addition of protecting against cross-contamination and cleanliness issues does not raise new questions regarding safety.
Fluid Collection Disposable	Manifold and Collection Liner	Manifold and Canister	-	The addition of a collection liner for containment of the waste fluid does not raise new questions regarding safety.
Product Code	BTA, Powered Suction Pump	FYD, Apparatus, Exhaust, Surgical	BTA, Powered Suction Pump	SAME

Design Feature	**Proposed Device** Cardinal ORwell™ Surgical Fluid Waste Collection and Disposal System	**Predicate Device** Stryker Neptune Waste Management System (K012991)	**Predicate Device** Neomedix Corporation, SupraFlow Console (K040239)	Comments
FDA Regulation, 21 CFR	878.4780	878.5070	878.4780	SAME
Dimensions – Mobile Unit	23" width x 28" depth x 47" height	18" width x 25" depth x 51" height	-	Dimensional differences do not affect safety or effectiveness
Dimensions – Disposal Station	34" width x 15" depth x 50" height	25" width x 22" depth x 21.5" height (Measured – not specified in 510(k))	-	Dimensional differences do not affect safety or effectiveness
Mobile Unit Electrical Requirements	UL 60601-1 Compliant AC Powered, 115 V, 12 Amps	UL 2601 Compliant AC Powered, 110 V, 16 Amps	-	Voltage and amperage differences do not raise new questions of safety and effectiveness.
Disposal Station Electrical Requirements	115 V, 4 Amps	120 V, 3 Amps	-	Voltage and amperage differences do not raise new questions of safety and effectiveness.
Suction Source	On-Board Pump	On-Board Pump	-	SAME
Mobile Unit Vacuum Range	0-19" Hg	0-19" Hg	-	SAME
Flow Rate	On 100% vacuum Fluid Flow Rate must be $\geq$ 5.0 LPM	Unknown	-	Requirement met (using water) for high volume
Vacuum Regulator	Knob-Controlled Bleeder Valve	Knob-Controlled Bleeder Valve	-	SAME
Fluid Suction Filter	HEPA, 99.97% efficiency @ 0.3 microns	HEPA, 99.97% efficiency @ 0.3 microns	-	SAME
Emergency Back-Up Port	Yes	Yes	-	SAME

Design Feature	**Proposed Device** Cardinal ORwell™ Surgical Fluid Waste Collection and Disposal System	**Predicate Device** Stryker Neptune Waste Management System (K012991)	**Predicate Device** Neomedix Corporation, SupraFlow Console (K040239)	Comments
Single Patient Use	Single	Single or Multiple Patients	-	The indication for single use in the proposed device increases clinician/patient safety by not allowing clinicians to leave a contaminated device in the OR for prolonged periods of time. This change does not raise new questions regarding effectiveness.
Canister Capacity	20 L	20 L	-	SAME
Suction Mode	Continuous	Continuous	-	SAME
OTC or Prescription	Prescription (RX only)	OTC	-	Devices are intended to be used in operating rooms, surgical centers, and doctor's offices.
Overflow Prevention Mechanism	Yes	Yes	-	SAME
Pre-Filter	Single Use Disposable	Single Use Disposable	-	SAME
Suction Inlet Port Dimensions	¼ inch inner diameter	3/8 inch inner diameter	-	Port size and design based off of currently acceptable Cardinal Health suction canister design.

Design Feature	**Proposed Device** Cardinal ORwell™ Surgical Fluid Waste Collection and Disposal System	**Predicate Device** Stryker Neptune Waste Management System (K012991)	**Predicate Device** Neomedix Corporation, SupraFlow Console (K040239)	Comments
Principles of Operation	• Fluid suctioned through suction wand into Disposable housed in Mobile Unit • Mobile Unit is moved to Disposal Station and fluid connections engage automatically • Contents are pumped out of Mobile Unit directly into hospital waste line • Disposable is comprised of a suction manifold and attached collection liner • Disposable connects to vacuum line in mobile unit and is housed in cylindrical canister	• Fluid and smoke are suctioned from a wand into the Rover • Rover is moved to docking station and fluid connections engage automatically • Contents are pumped into the Docking Station tank • Fluids pumped down a drain • Fluid is suctioned through a manifold with an anti-reflux feature • Manifold connects to top of a 20 L canister on the Rover which has a spray head inside	-	The Manifold in the predicate has been augmented into a Disposable in the proposed device. This change enhances safety of the clinician and patient since all portions of the device which contact surgical fluid waste will be disposed into red bag waste and not left in the OR. The proposed change does not affect device effectiveness.

Summary of Testing:

The ORwell™ Fluid Collection and Disposal System is substantially equivalent to the predicate device. The testing consisted of all testing identified in the FDA's Guidance Document for Powered Suction Pumps, September 30, 1998 and Premarket Submission for Software Contained in Medical Device. A hazard analysis of the system and its software was performed and testing was conducted to validate the systems overall operations. The ORwell™ Fluid Collection and Disposal System has no direct patient contact therefore, biocompatibility testing is not applicable. A detailed list of testing is provided with test protocols and reports.

The following testing was completed on the ORwell™ System:

1. *"Almost Full" Sensor* – verification that light illuminates and audible alarm sounds at the appropriate pre-determined level
2. *Vacuum Level Operating Range* – verification that, with regulator, vacuum operating range is within spec
3. *Fluid Suction Flow Rates* – verification that typical worst case and maximum fluid suction flow rates are within spec
4. *HEPA Filter Efficiency and Life* – verification that filter assembly is HEPA efficient and has a life of ≥ 500 hours
5. *Fluid Trap Shutoff* – fluid trap assembly tested for fluid ingress effectiveness
6. *Overflow Valve Fluid Ingress* – overflow valve tested for fluid ingress effectiveness
7. *Instructions for Use* – ORwell™ system tested for safe operation when being used per instructions for use
8. *Disposal Station Valve Drip* – verification that no dripping results after the fluid disposal process
9. *Disposal Port Valve Opening Pressure* – verification that the valve will prevent user from being exposed to biohazards

Performance Data

The ORwell™ Fluid Collection and Disposal System was tested against the predicate for vacuum level operating range and fluid suction flow rate. Vacuum level operating range was found to be the same at 0" – 19" Hg and maximum fluid suction flow rate was found to be comparable with ORwell™ performing at approximately 5 liters/minute and the predicate at approximately 4.9 liters/minute.

Conclusions Drawn from Testing

Data from testing demonstrates that the performance of the ORwell™ Fluid Collection and Disposal System is similar and substantially equivalent to that of Stryker's currently commercially available Neptune Waste Management System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Cardinal Health
% Underwriters Laboratories, Inc.
Mr. Ned Devine
333 Pfingsten Road
Northbrook, Illinois 60062-2096

APR 30 2008

Re: K080845
Trade/Device Name: Orwell™ Fluid Collection and Disposal System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: JCX
Dated: April 16, 2008
Received: April 17, 2008

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

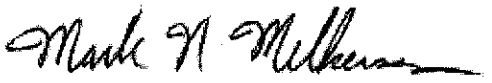
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080845

Device Name: ORwell™ Fluid Collection and Disposal System

Indications for Use:

The ORwell™ Fluid Collection and Disposal System is intended to be used in the Operating Rooms, Surgical Centers, and Doctors' Offices to collect and dispose of fluid waste.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080845